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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
EV31030US

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Application Number	Filed
10/724,816	December 1, 2003

First Named Inventor: Thomas L. Clubb

Art Unit	Examiner
3767	Elizabeth R. MacNeill

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☑ attorney or agent of record.
Registration number 33,984.

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

/Patrick J. O'Connell/
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February 25, 2009
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

REMARKS

Claims 1, 3 to 6, 12 to 17, 29, 33, 35, 36, 38, 42, 43, 45 to 48, 50 to 53, 59 to 65, 71 and 72 are finally rejected as being anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 4,979,951 ("Simpson") and claims 18 to 28 are finally rejected under 35 U.S.C. 103(a) as unpatentable over Simpson. The Examiner's grounds for rejecting those claims are set forth in the Final Office Action dated October 28, 2008 (the "Final Office Action") and the Advisory Action dated January 7, 2009 (the "Advisory Action"). Applicant responded to the Final Office Action in a Response filed December 18, 2008 (the "Response"). Claims 1, 36, 42, 43, 45, and 72 are the only pending independent claims and will be the focus of these remarks.

Applicant requests a pre-appeal brief review of the final rejection of these claims for the following reasons:

(1) The Examiner's rejection of claims 1, 36, 42, 43, 45, and 72 as being anticipated by Simpson is in error because the rejection is based upon the Examiner's incorrect interpretation of the structure and features of the device disclosed in Simpson.

(2) The Examiner's rejection of claims 42, 43 and 45 as being anticipated by Simpson is further in error because the Examiner has failed to consider positive limitations which clearly distinguish those claims over Simpson.

Each of the independent claims has certain features in common. Each is directed to a catheter (claims 1 and 36), an assembly including a catheter (claims 42 and 43), or a method for positioning a catheter (claims 45 and 72). In each of these claims the catheter is claimed as comprising first, second and third elongate tubular bodies and an elongate member which joins the first and second elongate bodies. Further, the third elongate tubular body is slidable within the lumen of the first elongate tubular body. Claim 42 includes the further limitation that "the third elongate tubular body having a length less than a length of the first elongate

tubular body". Claim 43 is directed to an assembly comprising an "embolic protection device" and a catheter. The method of claim 45 includes disposing a guide wire "proximal end within the lumen of the second elongate tubular body and not within the lumen of the first elongate tubular body". In rejecting these claims the Examiner states that Simpson teaches a catheter in FIG. 3 that has a "first elongate tubular body (108) having a proximal portion (46, Fig 1A), a distal portion (at 101b, just before notch 102), and a lumen extending between the proximal and distal end (Fig 4); [a] second elongate tubular body (101a) having a proximal end (at 128, just after notch 102) and a distal end (see Fig 3 where guide wire 113 extends from the distal end) and a lumen (guide wire lumen 111); [a]n elongate member (101, only section with notch 102) joining the first and second tubular bodies; [f]urther comprising a third elongate member (106) having a proximal portion (cable 116) and a distal portion (cutting edge 157, Fig 7) and a lumen . . . [a]t least the proximal portion of the third elongate body being disposed within the lumen of the first body (Fig 2C) and being slidable so that the distal portion of the third body is within the second body (Fig 2D)". (Final Office Action, page 2 and 3, paragraph 2).

Applicant responded to the Final Office Action setting forth in detail why Simpson does not anticipate claim 1 (see Response, paragraph bridging pages 2 and 3), claim 36 (see Response, paragraph bridging pages 3 and 4), claim 42 (see Response, page 4), claim 43 (see Response, paragraph bridging pages 4 and 5), claim 45 (see Response, paragraph bridging pages 5 and 6) and claim 72 (see Response, page 6). Applicant will not repeat those arguments herein. However, one of the features that was discussed in the Response was the requirement that the proximal end of the third elongate tubular body be "maintained within" (claims 1, 36, 43, 45 and 72) or be "within" the lumen of the first elongate tubular body (claim 42) and that the feature as specifically set forth in the claims was not disclosed in Simpson. In the Advisory Action the Examiner stated that "Applicant's arguments are not persuasive because in Fig 1 clabe [*sic*] 36/116

terminates at U-shaped member 48, as does the tube 108" and that "'[f]lexible drive means 41' is connected to the second end of u-shaped member 47, NOT THE CABLE."

The Examiner's misunderstanding of the device disclosed in Simpson is clear. Simpson discloses several embodiments of an atherectomy device and methods of using those embodiments. A first embodiment is disclosed in FIGS. 1A and 1B. A second embodiment is disclosed in FIGS. 3 to 5. A third embodiment is disclosed in FIGS 6A and 6B. These embodiments have various elements which are similar both structurally and functionally and the Examiner, in rejecting the claims, refers not only to the embodiment of FIG. 3 in describing the Simpson device but also to each of the other embodiments in identifying certain features or elements of the device. The error in the Examiner's analysis is in failing to compare corresponding elements of the embodiments. Specifically, in the embodiment of FIGS. 3 to 5 Simpson discloses an atherectomy device that includes a guiding means 107 comprising a tube 108, a drive means comprising cable 116 connected at its distal end to a cutter 106, and a housing 101 connected to a distal end of the guiding means. Housing 101 comprises a rounded distal extremity 101a and a rounded proximal extremity 101b. (Simpson, Col. 6, line 42 to Col. 7, line 2). As described above, in comparing this structure to the pending claims the Examiner states that the tube 108 (the guiding member) is the first elongate tubular body having a distal portion comprising a proximal portion of the housing including the rounded portion 101b and a proximal portion comprising control means 46 as shown in FIG. 1A (FIG. 3 does not show the control means). The Examiner further states that a distal portion of the housing including rounded portion 101a is the second elongate tubular member, the housing 101 with notch 102 is the elongate member, and the combination of the cutter 106 and the drive means 116 comprises the third elongate tubular member. The embodiment of FIGS. 1A and 1B has corresponding elements including a guiding means 36 (comprising coil spring 37 and tubular member 38) (Simpson, Col. 3, lines 28 to

41), a drive means 41 (comprising coil spring 42 and tubular member 43) (Simpson, Col. 3, lines 44 to 47), and a housing 12 with rounded distal and proximal extremities (Simpson, Col. 2, lines 61 to 63). In the portions of the Response referenced above Applicant pointed out to the Examiner that the claims were not anticipated by Simpson for at least the reason that the proximal end of drive cable 116 is not maintained within the lumen of the guiding means. In support of that conclusion Applicant cited Simpson at Col. 7, lines 2 to 7 which compares the manner in which the devices of the embodiments of FIG. 3 and FIG. 1 are connected to the control means and which states that the "tube 108 can be secured to the leg 48 of the U-shaped member 47 in the same manner that the guiding cable 36 is secured thereto" and that "cable 116 can be secured to the knob 52 in the same manner that the flexible drive means 41 is secured to the knob 52." Thus, Simpson makes it clear that the proximal end of the drive means 116 (the third elongate tubular body) is connected at a location proximal to the proximal end of the guiding means 108 (the first elongate tubular body) and is thus not maintained within the lumen of the guiding means. However, the Examiner, in responding to these arguments in the Advisory Action confuses the embodiments and erroneously equates the drive means 116 of FIG. 3 with the guiding means 36 of FIGS. 1A and 1B instead of with the drive means 41. This results in the Examiner wrongfully concluding that cable 116 terminates at U-shaped member 48 instead of at member 47.

In a telephone interview with the Examiner Applicant pointed out to the Examiner the errors in the Advisory Action. Additionally, Applicant noted that the purpose of the drive means is to provide for advancement and rotation of the cutting means through the housing as shown, for example, in FIGS. 2B to 2D. (Simpson, Col. 5, line 67 to Col. 6, line 2). In order for the device to function as described the drive means must necessarily extend past the proximal end of the guiding means (tube) to allow for connection to the control means and to allow the cutter to be manipulated by the operator. Therefore, Simpson does not anticipate

these claims. As noted in the Interview Summary dated January 27, 2009 the Examiner responded by stating "it would be obvious to extend 36 over 41 up to the knob 52/54 without affecting the function of the device." Applicant submits that such modification is neither taught nor suggested by Simpson and would provide no obvious structural or functional improvement to the device. As a matter of fact, such modification would likely reduce in whole or part the functionality of the device since it would interfere with the movement of the screw 52 between legs 48 and 49 of control handle 47 and compromise operation of the control means.

In addition to the reasons set forth above claims 42, 43, and 45 as well as claims 46 to 48, 50 to 53, 59 to 65, 69 and 71 which depend from claim 45 are allowable for additional reasons. Claim 42 recites the "third elongate tubular body having a length less than a length of the first elongate tubular body ". Simpson clearly does not disclose this feature. In Simpson the third elongate tubular body (drive means 116) is longer than the first elongate tubular body (tube 108). Claim 43 is directed to an assembly comprising an "embolic protection" device and a catheter. Claim 43 further recites that "the embolic protection device being moveable from the lumen of the third elongate tubular body to the lumen of the second elongate tubular body". Simpson does not disclose an embolic protection device that is moveable from the lumen of the drive means/cutter to the distal portion of the housing. Claim 45 is directed to a method of positioning a catheter and includes "disposing the guide wire proximal end within the lumen of the second elongate tubular body and not within the lumen of the first elongate tubular body". Simpson does not disclose a method of positioning a catheter where a guide wire is positioned within the distal portion of the housing but not within the guiding means including the proximal portion of the housing. For these additional reasons claims 42, 43, and 45 and the claims which depend therefrom are allowable.